Guidance document: 76-21.1:15
Department of Health Professions
Enforcement Division

Commonwealth of Virginia **Date_____**
Department of Health Professions
6603 Board Street Road, 5th Floor
Richmond, Virginia 23230

COMPOUNDING PHARMACEUTICAL PRPODUCTS
INSPECTION REPORT
Rev: 9/2003

Name_____ License No._____

DESIGNATIONS: C MEANS COMPLIANT, NC MEANS NON-COMPLIANT

54.1-3410.2 PHARMACISTS' AUTHORITY TO COMPOUND UNDER CERTAIN CONDITIONS

A pharmacist may engage in compounding of drug products when the dispensing of such compounded products is (i) pursuant to valid prescriptions for specific patients and (ii) consistent with the provisions of § 54.1-3303 relating to the issuance of prescriptions and the dispensing of drugs

PHYSICAL AND EQUIPMENT REQUIREMENTS FOR PHARMACIES PREPARING STERILE PRODUCTS
18 VAC 110-20-413

C	NC	
_____	_____	The sterile compounding area shall be of sufficient size to accommodate a laminar airflow hood and to provide for the proper storage of drugs and supplies used in aseptic processing
_____	_____	The sterile compounding area where parenteral products are routinely prepared shall be isolated from other areas and other pharmacy functions.
_____	_____	Sterile compounding shall be performed within a laminar flow hood or other appropriate environmental control device capable of maintaining, during normal activity, at least Class 100 conditions in the work area where sterile compounding is performed.
_____	_____	Compounding of cytotoxic preparations shall be performed in a vertical flow Class II biological safety cabinet.

A PHARMACY PREPARING STERILE PRODUCTS SHALL MAINTAIN SUPPLIES ADEQUATE FOR THE ASEPTIC PREPARATION OF STERILE PRODUCTS INCLUDING, BUT NOT BE LIMITED TO THE FOLLOWING:

_____	_____	Antimicrobial soap
_____	_____	Hot and cold water supply easily accessible to the sterile compounding area for hand washing prior to aseptic compounding
_____	_____	Appropriate apparel for personnel performing sterile compounding
_____	_____	Suitable disposal containers for used needles, syringes, etc. and, if applicable, containers for cytotoxic waste and infectious waste
_____	_____	A pharmacy preparing sterile products shall have sufficient current reference materials related to sterile products consistent with the policy and procedure manual and with the types of products prepared.
_____	_____	The pharmacy preparing sterile products shall have equipment necessary for maintaining and monitoring required temperature storage conditions both in the pharmacy and during delivery to the patient, if applicable.

LABELING OF COMPOUNDED PRODUCTS

THE CONTAINER IN WHICH THE DRUG IS DISPENSED SHALL CONTAIN THE FOLLOWING INFORMATION:

54.1-3410

_____	_____	Prescription serial number or name of the drug
_____	_____	Date of initial filling
_____	_____	Name and address of the pharmacy
_____	_____	Name of the patient or, if the patient is an animal, the name of the owner of the animal and the species of the animal
_____	_____	Name of the prescriber by whom the prescription was written, except for those drugs dispensed to a patient in a hospital pursuant to a chart order
_____	_____	Directions as may be stated on the prescription.
_____	_____	Drug name and strength, when strength is applicable
_____	_____	For any drug product possessing a single active ingredient, the generic name of the drug
_____	_____	If a generic drug is dispensed when a prescription is written for a brand name drug the label shall contain the generic name followed by the words "generic for" followed by the brand name of the drug prescribed, and the

label shall also contain the generic's brand name or the manufacturer or distributor of the drug dispensed

____ ____ Number of dosage units, or if liquid, the number of milliliters dispensed

18 VAC 110-20-414

C	NC	
_____	_____	The label of a compounded sterile product shall include all active ingredient names, strengths, amounts, and concentrations, when applicable, and for IV infusion shall include the name of all solutions.
_____	_____	The label of a compounded parenteral sterile product shall include an appropriate beyond-use date and time, if applicable, and the required storage conditions to assure product integrity for that time period.
_____	_____	Unless otherwise specified and justification provided in the policy and procedure manual, the expiration date for **unpreserved** sterile products prepared aseptically in a closed system for a single patient shall bear a maximum beyond-use date, including administration, as follows: 1. Twenty-eight hours if stored at controlled room temperature; 2. Seven days if stored under refrigeration; and 3. Thirty days if stored under freezing conditions.
_____	_____	The label of other compounded sterile products shall bear an appropriate beyond use date, not to exceed 30 days from the date of preparation.
_____	_____	If the product is for home or other out-patient use, the label shall bear the prescribed administration regimen including rate and route of administration and any device specific instructions.
_____	_____	The label shall bear any appropriate auxiliary labeling, including precautions for cytotoxic drugs.

54.1-3410.2

_____ _____ Pharmacists shall label all compounded drug products that are dispensed pursuant to a prescription in accordance with this chapter and the Board's regulations, and shall include on the labeling an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding.

PHARMACISTS SHALL LABEL ALL PRODUCTS COMPOUNDED PRIOR TO DISPENSING, IN ANTICIPATION OF PRESCRIPTIONS, WITH:

_____ _____ Name and strength of the compounded medication or a list of the active ingredients and strengths
_____ _____ Pharmacy's assigned control number that corresponds with the compounding record
_____ _____ Appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding
_____ _____ Quantity compounded

PHARMACISTS SHALL LABEL ALL COMPOUNDED PRODUCTS DISTRIBUTED TO PRACTITIONERS FOR ADMINISTRATION TO THEIR PATIENTS WITH:

_____ _____ The statement "For Administering in Prescriber Practice Location Only"
_____ _____ Name and strength of the compounded medication or list of the active ingredients and strengths
_____ _____ Facility's control number
_____ _____ Appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding
_____ _____ Quantity compounded

RECORDS FOR COMPOUNDED PRODUCTS

54.1-3410.2

PHARMACISTS SHALL MAINTAIN RECORDS OF ALL COMPOUNDED DRUG PRODUCTS AS PART OF THE PRESCRIPTION, FORMULA RECORD, FORMULA BOOK, OR OTHER LOG OR RECORD. RECORDS MAY BE MAINTAINED ELECTRONICALLY, MANUALLY, IN A COMBINATION OF BOTH, OR BY ANY OTHER READILY RETRIEVABLE METHOD. ALL COMPOUNDING RECORDS SHALL INCLUDE:

_____ _____ Date of the preparation
_____ _____ Generic name and the name of the manufacturer of the raw materials or the brand name of the raw materials
_____ _____ Manufacturer's lot number and expiration date for each component, and, when the original manufacturer's lot number and expiration date are unknown, the source of acquisition of the component
_____ _____ Prescription number or the assigned lot number when compounding in anticipation of receiving a prescription
_____ _____ Signature or initials of the pharmacist or other authorized person performing the compounding
_____ _____ Signature or initials of the pharmacist responsible for supervising support personnel and conducting in-process and final checks of compounded products when other authorized personnel perform the compounding function
_____ _____ Quantity in units of finished products or quantity of raw materials used in compounding the product

the package size and the number of units prepared

_____ _____ Beyond-use date and the criteria used for determining this date

FOR LEVELS OF COMPOUNDING ASSOCIATED WITH HIGHER RISK FROM CONTAMINATION IN COMPOUNDING, RADIOPHARMACEUTICALS, PREPARATION OF DOSAGE FORMS THAT ARE DOSE-CRITICAL OR ARE SPECIALIZED PREPARATIONS:

C	NC	
_____	_____	A complete formula with compounding procedures, including, when appropriate, complete mixing instructions with the order of mixing, mixing temperatures or other environmental controls, duration of mixing, equipment needed, and other factors necessary to replicate the preparation as compounded
_____	_____	Documentation for the levels of compounding of any tests conducted on compounded products in accordance with the required policy and procedure manual.

18 VAC 110-20-416 IN ADDITION TO OTHER REQUIRED RECORDS, THE FOLLOWING ADDITIONAL RECORDS SHALL BE MAINTAINED FOR STERILE COMPOUNDING:

_____	_____	Record documenting certification of clean room or laminar flow hoods.
_____	_____	If sterile products are provided to a patient's residence, a record documenting training of the patient or caregiver or both in the proper storage and use of the product and any devices used to administer the devices.
_____	_____	Compounding records maintained on or with the original prescription, or in a log format which can be cross-referenced with the prescription, or in an automated data processing system which contains the same information required in a manual system and is capable of producing a hard copy print-out of a two year history of prescription compounding and dispensing upon request within 72 hours.

IN ADDITION TO PRESCRIPTION INFORMATION, THE RECORD MUST INCLUDE THE FOLLOWING INFORMATION:

_____	_____	Date of sterile compounding;
_____	_____	Beyond-use date assigned to the sterile product
_____	_____	Signature, initials, or electronic identification of pharmacist compounding, or of both the non-pharmacist compounding and pharmacist checking the compounding of the sterile product, and;

POLICY & PROCEDURE MANUAL

NOTE: A policy and procedure manual shall not be required for nonsterile compounding that only involves the mixing of two or more commercially available preparations, the mixing or reconstitution of a commercially available product in accordance with the manufacturer's instructions, preparation of injections for immediate administration using commercially available sterile products, preparation of other nonsterile dosage forms that are not dose-critical or specialized products, and the addition of flavoring.

54.1-3410.2 PHARMACISTS SHALL MAINTAIN AND COMPLY WITH A POLICY AND PROCEDURE MANUAL WHEN ENGAGING IN THE LEVELS OF COMPOUNDING OF DRUG PRODUCTS ASSOCIATED WITH HIGHER RISK FROM CONTAMINATION IN COMPOUNDING, RADIOPHARMACEUTICALS, OR PREPARATION OF DOSAGE FORMS THAT ARE DOSE-CRITICAL OR ARE SPECIALIZED PREPARATIONS. THE MANUAL SHALL:

_____	_____	Be consistent with USP-NF standards and guidance for compounding
_____	_____	Describe all significant procedures in compounding
_____	_____	Establish a quality assurance program to ensure accountability, accuracy, quality, safety, and uniformity.

18 VAC 110-20-412 A POLICY AND PROCEDURE MANUAL SHALL BE PREPARED AND MAINTAINED FOR THE COMPOUNDING, DISPENSING AND DELIVERY OF STERILE PRODUCTS AND SHALL INCLUDE AT LEAST THE FOLLOWING ELEMENTS:

_____	_____	Personnel qualifications including initial and follow-up training and method of periodic re evaluation of qualifications and performance;
_____	_____	Scope of compounding performed at the pharmacy and proper procedures for compounding to include maintaining suitable environmental conditions in the compounding area, wearing appropriate garb to reduce particulate matter and contamination of work area, performing aseptic procedures.
_____	_____	Procedures for maintaining and monitoring proper operating conditions for all equipment used in sterile compounding;
_____	_____	Guidelines for patient or caretaker education if products are dispensed for home use to include instructions concerning proper storage, aseptic manipulation of the product, proper administration and use of devices if applicable, recognizing signs of instability or incompatibility, and procedures in case of an emergency with the product;
_____	_____	Guidelines for assignment of beyond-use dates for all compounded sterile products and justification for any date chosen which exceeds the standard set forth in this regulation.
_____	_____	Separate procedures for handling cytotoxic drugs, if applicable, to include protective apparel; disposal procedures consistent with applicable local, state, and federal requirements; procedures for handling spills; special packaging

and labeling requirements, and delivery procedures to minimize risks of accidental spills;

_____ _____ If applicable, separate procedures for compounding sterile products using non-sterile components or open system transfer techniques and for end-product sterilization of these products.

QUALITY ASSURANCE

54.1-3401.2

C	NC	
_____	_____	Pharmacists shall personally perform or personally supervise the compounding process, which shall include a final check for accuracy and conformity to the formula of the product being prepared, correct ingredients and calculations, accurate and precise measurements, appropriate conditions and procedures, and appearance of the final product.

18 VAC 110-20-415

_____	_____	The pharmacist-in-charge in a pharmacy compounding sterile products shall be responsible for maintaining and updating the policy and procedure manual as set forth in 18 VAC 110-20-411 in accordance with current acceptable standards, and for ensuring compliance with the policy and procedure manual.
_____	_____	All laminar flow hoods or other environmental control devices shall be certified according to accepted standards for operational efficiency by a qualified independent contractor at least every six months.

OTHER

54.1-3410.2

_____	_____	Pharmacists may compound using ingredients that are not considered drug products in accordance with the USP-NF standards and guidance on pharmacy compounding.

PHARMACISTS MAY USE BULK DRUG SUBSTANCES IN COMPOUNDING WHEN SUCH BULK DRUG SUBSTANCES:

_____	_____	Comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if such monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding; or are drug substances that are components of drugs approved by the FDA for use in the United States; or are otherwise approved by the FDA;
_____	_____	Are manufactured by an establishment that is registered by the FDA; or
_____	_____	Are distributed by a licensed wholesale distributor or registered nonresident wholesale distributor, or are distributed by a supplier otherwise approved by the FDA to distribute bulk drug substances if the pharmacist can establish purity and safety by reasonable means, such as lot analysis, manufacturer reputation, or reliability of the source.

PHARMACISTS SHALL NOT ENGAGE IN THE FOLLOWING:

_____	_____	1. The compounding for human use of a drug product that has been withdrawn or removed from the market by the FDA because such drug product or a component of such drug product has been found to be unsafe. However, this prohibition shall be limited to the scope of the FDA withdrawal; or 2. The regular compounding or the compounding of inordinate amounts of any drug products that are essentially copies of commercially available drug products. However, this prohibition shall not include (i) the compounding of any commercially available product when there is a change in the product ordered by the prescriber for an individual patient, (ii) the compounding of a commercially manufactured drug only during times when the product is not available from the manufacturer or supplier, or (iii) the mixing of two or more commercially available products regardless of whether the end product is a commercially available product.

This facility has been inspected by an inspector of the Department of Health Professions. The results of the inspection have been noted. I acknowledge that the noted conditions have been deemed by the inspector as not being in compliance and have been explained to me and that I have received a copy of the inspection report.

Signature of Inspector Date Signature of Licnesee Date